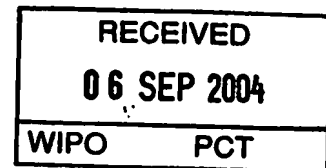


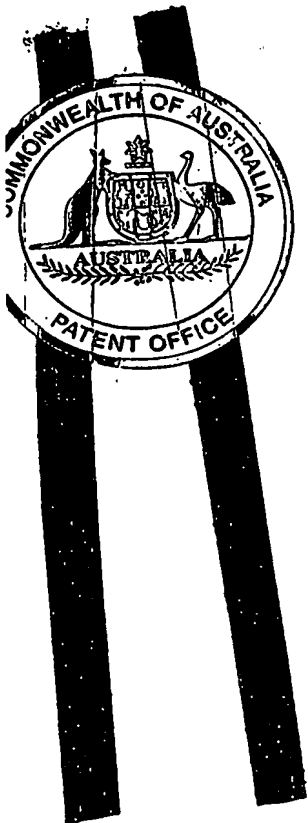


Patent Office
Canberra



I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003903990 for a patent by MEDIGARD PTY LTD as filed on 31 July 2003.

BEST AVAILABLE COPY



WITNESS my hand this
Eleventh day of August 2004

A handwritten signature in black ink, appearing to be 'L. Mynott'.

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
AND SALES

**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

CANNULA/CATHETER INTRODUCER

Field of Invention

The present invention relates to cannula/catheter introducer devices and has particular relevance to such devices with retractable needles.

5

Background Art

Catheter insertion devices are well known in the art. When a catheter is inserted into a patient for the intravenous delivery of a fluid, a disposable needle passing through the catheter cannula is utilized to make a
10 puncture to permit entry of the tip of the cannula into the patient. The needle is then withdrawn leaving the catheter in place either for a direct hook up to a bottle of fluid to be delivered, or to be capped for later use. The needle which is now contaminated with blood or other body fluid must be disposed of
15 without creating a risk of needle sticks to medical personnel which are engaged in the operation of inserting a catheter. A danger to clean up and medical waste disposal personnel continues if the used needles are not rendered harmless in some way. Caps or covers that can be mounted over the needle are not a satisfactory solution because they must be put in place and can come loose and expose the used needle.

20 A discussion of the problems associated with various approaches and uses of cannula insertion products is found in Kulli, U.S. Pat. No. 4,747,831.

Retractable needles have been recognized as the best solution of these problems.

25 A number of these approaches are disclosed in U.S. Pat. No. 4,747,831, mentioned above, which includes an external latch mechanism which is pushed to release a spring loaded needle which is withdrawn into the chamber of the device. Some embodiments have a sliding block and retractable fingers which depress spring loaded ears to allow retraction of the
30 needle holder, ratcheting devices which unlatch the needle holder by rotation of parts and even frangible parts which are broken when a plunger is pushed forward.

Dysarz, U.S. Pat. No. 5,129,884 is another example of an external latch which may be disengaged to allow a needle holder to withdraw a needle into the main body of the device.

5 Walter, U.S. Pat. No. 4,828,548 discloses a holder having a piston which may be operated on by vacuum to withdraw a needle.

Erskine, U.S. Pat. No. 5,501,675 is a more recent version of a latch operated device wherein a needle holding part may be released with an external latch.

10 The devices of the prior art have complicated parts which are difficult to manufacture and especially difficult to assembly in a high speed manufacturing operation. Many of them are prone to premature firing during handling and with some it is difficult to know when the needle is safe. Disengagement of the catheter assembly from the retraction device is not fully
15 under the timing and control of the medical operator because retraction results in immediate separation of the device from the cannula assembly.

It is an object of the present invention to provide a simplified cannula/catheter introducer which is safe to use and can be produced at a modest cost.

20 Further objects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

Disclosure of Invention

25 According to the present invention, there is provided a cannula/catheter introducer comprising:

- (a) a cannula and catheter connector assembly,
- (b) a retractable needle assembly for assembly with the cannula and catheter assembly, and
- (c) a valving member connected with the cannula and
30 catheter assembly for controlling in ingress and egress of fluids from a patient.

The cannula and catheter connector assembly may be provided

with an inlet tube for releasable assembly with an outlet tube of a retractable needle.

The valving member is manually adjustable from a first sealing position to a second flow position.

5 The valving member is a plunger type valve.

The retractable needle comprises an outer and inner casing, an outlet from the casing, an internal piston within the inner casing mounting a needle and a sealed compartment between the piston and a closed end of the inner casing.

10 The sealed compartment contains partial pressure.

The outer casing is provided with wings for gripping.

The piston may include a transparent vial section which enables a user to establish that the needle has been correctly inserted.

The vial has a minute venting aperture.

15 With the present invention, the assembled catheter introducer is handled as a unit. When the operator verifies that the needle is properly inserted, one hand can hold the connector that remains attached to the patient while the other hand separates the retraction body which upon separation is automatically retracted. A portion of the hand rests against the
20 cannula to prevent blood flow until the other hand inserts the conventional tube into the catheter connector to start the infusion of fluid. Immediately after separation the retraction body safely contains the retracted needle and the removed part is safely discarded.

25 Brief Description of the Drawings

Aspects of the present invention will now be described with reference to the accompanying drawings in which:

FIGURES 1 to 4 are longitudinal sectional drawings of a cannula/catheter introducer according to aspects of the present invention,
30 and

FIGURES 5 and 6 are enlarged sectional drawings of the cannula/catheter device of the present invention, and

FIGURE 7 is a perspective view of the device of the present invention assembled to a retractable needle.

With respect to the drawings, the present invention provides a cannula/catheter introducer combination comprising a cannula and catheter assembly generally indicated by arrow 1, and a retractable needle assembly generally indicated by arrow 2 for connection to the cannula/catheter combination.

The cannula/catheter assembly 1 is provided with a valving member generally indicated by arrow 3 for controlling the ingress and egress of fluids from a patient.

The cannula/catheter assembly is provided with an elongate body 4 having an inlet nozzle 5 and an outlet nozzle 6 and the valving member intersects with a valve body 7.

The inlet 5 and outlet 6 respectively provide a needle aperture 8 and a tapered socket 9 for connection with an outlet nozzle 10 of the needle assembly.

The valving member 3 includes a valve plunger 11 which is adjustable from a first sealing position (Figure 5) and a second flow position (Figure 6).

The plunger 11 has an aperture 12 therein supporting a resilient pierceable gasket 13. The gasket 13 allows a needle 14 to pass through it and when the needle is withdrawn it closes to seal off the needle penetration.

The plunger is also provided with a peripheral fluted portion 15 which when positioned in the fluid mainstream 16 (see Figure 6) allows fluid to pass in both directions.

O-ring seals 17 ensure fluid tight sealing.

The retractable needle assembly 2 comprises outer and inner tubes 18, 19 respectively with the inner tube 19 being a sliding fit in the outer tube 18.

The outer tube 18 has an open end 20 and is provided with finger gripping wings 21.

The outer tube 18 has a substantive elongate circular bore and

a tapered socket.

The inner tube 19 has a closed end 22 and an open end 23. .

A needle holding piston assembly generally indicated by arrow 24 is a sliding fit within the inner tube 19.

5 The piston assembly comprises a hollow tubular section 25 a needle mounting block 26, and a sealing member 28 at the rearward end of the piston. The rear seal 28 is mounted on a knob 29.

10 The piston assembly includes a transparent vial section 30 which enables medical staff to establish that the needle has been correctly inserted when blood flows to the vial and is visually detected.

 The open end 20 of the outer tube is provided with an internal shoulder 31 and the closed end 22 of the inner casing a complementary expanded portion 32 which ensures that the inner tube is secured within the outer tube.

15 The front end of the block 26 is provided with a plurality of raked fingers 27. In the ready-to-use and use situations illustrated by figures 1 and 2, the fingers are positively located adjacent the front end of the inner tube 19 as illustrated. To dislocate the fingers 27 the end 22 of the inner tube is pushed forward using the palm of the hand whilst gripping the wings 21 with
20 the fingers. The fingers are thereby forced into the tapered section of the nozzle 10 and compressed to the extent that the needle assembly is withdrawn under vacuum, the situation illustrated by figures 3 and 4.

 Figures 1 and 2 of the drawings show the fully assembled device as delivered for use, figure 3 of the drawings with the needle
25 withdrawn after use, and figure 4 separation of the cannula catheter from the needle assembly.

 Figures 5 and 6 of the drawings show alternative positions of the plunger 11 of the valving member 3.

30 In figure 5 the plunger 11 is in a first position with the gasket 13 blocking fluid flow.

 In figure 6, the plunger 11 has been manually repositioned and the fluted portion 15 provides a passage for fluid flow.

Figure 7 of the drawings is an assembly drawing of the device of the present invention in a ready-to-use condition.

Once the cannula/catheter device is secured and the needle assembly removed, the cannula/catheter can be used for the introduction or
5 withdrawal of fluids to and from a patient.

Aspects of the present invention have been described by way of example only and modifications and additions thereto may be made without departing from the spirit or scope thereof.

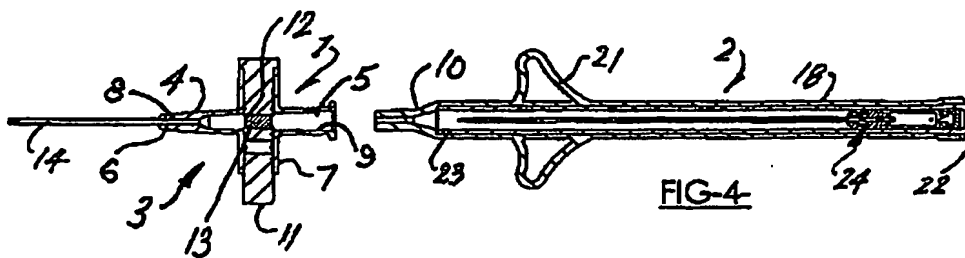
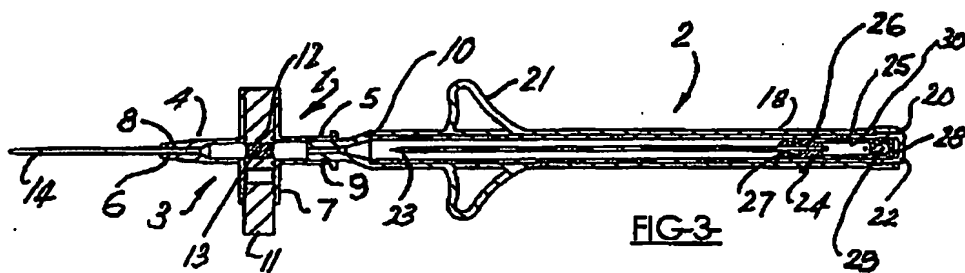
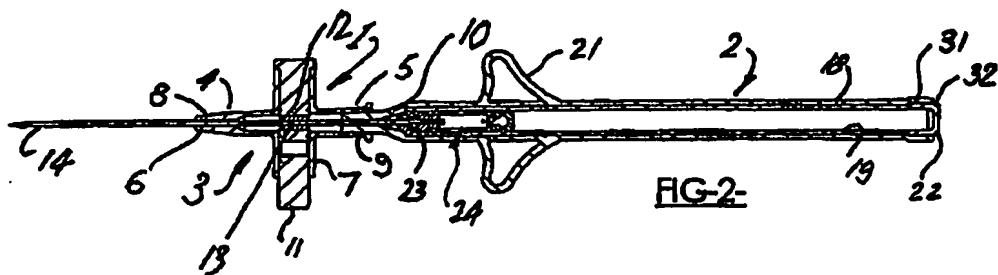
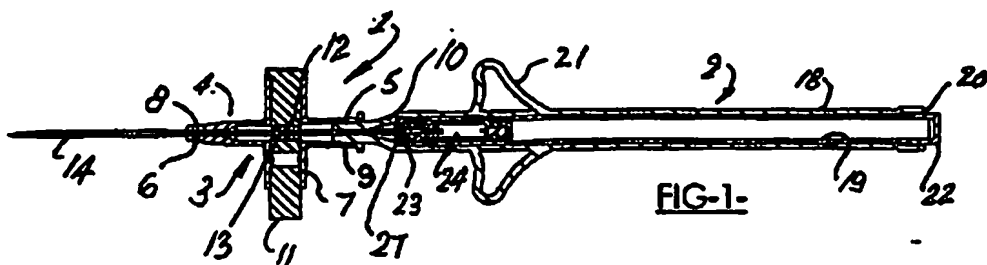
Dated this 31st day of July 2003

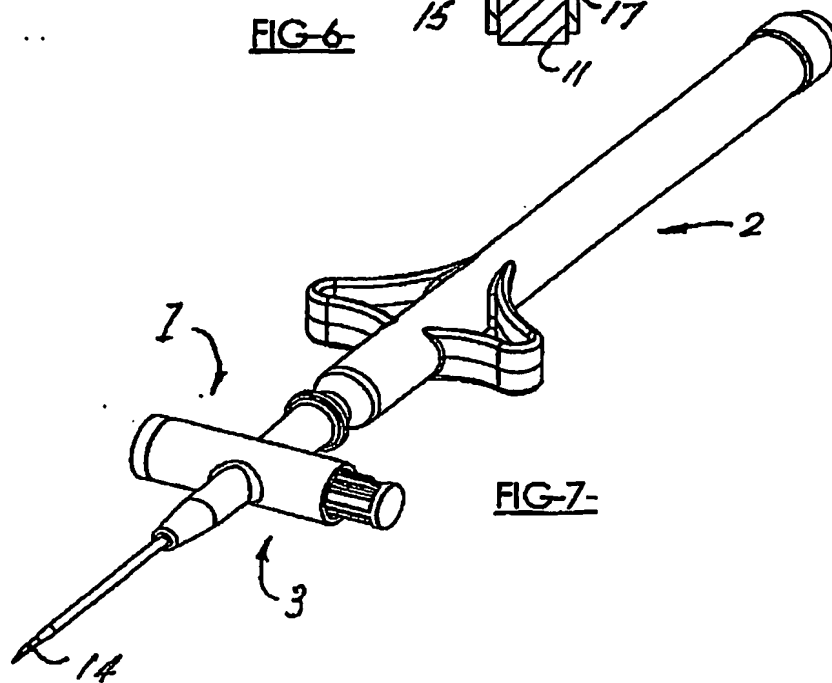
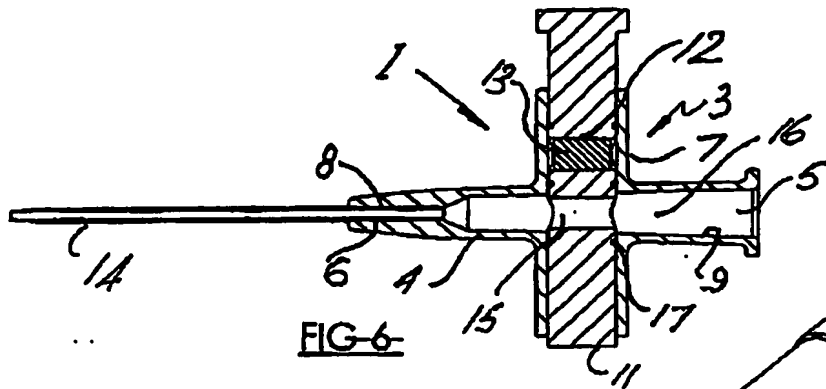
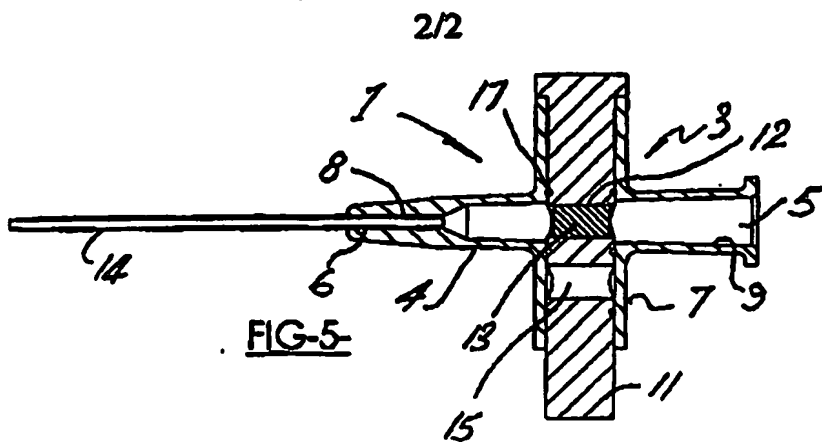
10

Medigard Pty Ltd

By its patent attorneys

Cullen & Co.





**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.